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| 10/599,542 | 09/29/2006 | Gary H. Graetz | 11398.72.1a.4 | 1533 |
| 22913 | 7590 | 10/14/2009 | EXAMINER | |
| Workman Nydegger 1000 Eagle Gate Tower 60 East South Temple Salt Lake City, UT 84111 | | | KIM, SUN U | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/599,542

Applicant(s)

GRAETZ ET AL.

Examiner

JOHN KIM

Art Unit

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-45 and 52-60 is/are pending in the application.
- 4a) Of the above claim(s) 56-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-45, 52-55, 59 and 60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. Newly submitted claims 56-58 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

New claims 56-58, drawn to a fluid filtration system having a combination of a fill container and a disposable pooling bag assembly of canceled claim 1, classified in class 210, subclass 252. Original invention of disposable pooling bag assembly and new invention (claims 56-58) are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because any other bag or any other pooling bag assembly can be used. The subcombination has separate utility such as storing solids or pooling liquids.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 56-58 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 40-45, 52-55 and 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekambaram et al (US Patent No. 6,071,005) in view of (US Patent No. 5,362,642).

Ekambaram et al teach a disposable pooling bag assembly comprising flexible pooling bag (1) having an interior surface bounding a single continuous compartment, the pooling bag having a first inlet port and a first outlet port directly communicating with the compartment, a circulation line (31, 32, 33) projecting outside the compartment of the pooling bag and having opposed ends in fluid communication with the compartment of the pooling bag via second inlet port and second outlet port wherein first fluid line (16) is connected to the first inlet port and second fluid line (13) is coupled to the first outlet port (see figures 1-2; col. 3, lines 1-54; col. 4, lines 1-48). Ekambaram et al further teach that the assembly is for transport, storage and mixing system for liquids which are sterile (see col. 3, lines 1-14).

Claims 40 and 59 essentially differ from the pooling bag assembly in reciting a filter having an inlet and an outlet and a fluid line extending from the outlet of the filter to the first inlet port of the pooling bag. Kern teaches a disposable pooling bag assembly comprising a filter (40) having an inlet and an outlet and a fluid line (66) in fluid communication with the inlet port (22) of the pooling bag (16) for providing sterile solution (see figures 1 and 4; col. 10, line 17-34; col. 12, lines 7-23). It would have been obvious to a person of ordinary skill in the art at the time of the invention was made to combine the filter of Kern with the disposable pooling assembly of Ekambaram et al to filter liquids to provide sterile liquids entering the flexible pooling bag.

Regarding claim 41, Ekambaram et al teach that 200 liter of fluid suspension was introduced into the flexible bag (1) and allowed to stand (see col. 6, lines 48-50); however,

Ekambaram et al does not teach the pooling bag having a volume of at least 500 liters. The only difference between the pooling bag of Ekambaram et al and the claim 41 is a recitation of relative dimension of the pooling bag and a pooling bag having the claimed relative dimension would not perform differently than the pooling bag of Ekambaram et al and is not patentably distinct from the pooling bag of Ekambaram et al.

In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

Regarding claim 42, Kern teaches that the filter (40) has a filter membrane with a porosity of 0.2 micron (see col. 10, lines 22-24).

Regarding claim 43, Ekambaram et al teach a dip tube (10 or 11) at least partially disposed within the compartment of the pooling bag (1) and being in fluid communication with the circulation line (31, 32, 33) (see figures 1-2; col. 4, lines 19-47).

Regarding claims 44 and 60, Ekambaram et al teach that a peristaltic pump (32) coupled with the circulation line (31, 32, 33) outside of the compartment of the pooling bag (1) (see figure 2; col. 4, lines 33-41).

Regarding claim 45, Ekambaram et al teach that an elongated fluid line (13) in fluid communication with the first outlet port on the pooling bag (1) (see figure 1; col. 3, lines 28-34; col. 4, lines 1-8).

Regarding claim 52, Ekambaram et al teach that a circulation line (31, 32, 33) projecting outside the compartment of the pooling bag and having opposed ends in fluid communication with the compartment of the pooling bag via second inlet port and second outlet port (see figures 1-2; col. 4, lines 33-48).

Regarding claim 53, Kern teaches that the inlet (64) of the filter (40) is isolated from the compartment of the pooling bag (16) (see figure 1; col. 12, lines 7-23).

Regarding claim 54, sealed sterile system within a packing bag is commonplace in the art of sterile medical apparatus. It would have been obvious to a person of ordinary skill in the art to seal assembled pooling bag, filter and circulation line in a sterile packing bag to avoid contamination or for delivery to a location of medical application.

Regarding claim 55, Ekambaram et al teach that the flexible container is sterilizable (see col. 3, lines 42-45). Kern also teaches that the flexible pooling bag (8), the filter (40) and the circulation line (52, 56, 58) are sterilizable (see figure 1; col. 8, lines 32-35; col. 10, lines 26-28; col. 7, line 65 – col. 12, line 53). The recitation of “the flexible pooling bag, the filter and the circulation line are concurrently sterilized as a preassembled, closed system” is not given patentable weight in the apparatus claim as this recitation is an intended use. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

5. Applicant's arguments with respect to claims 40-45, 52-55 and 59-60 have been considered but are moot in view of the new ground(s) of rejection.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOHN KIM whose telephone number is (571)272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Kim/
Primary Examiner, Art Unit 1797

JK
10/8/09